

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

THE RESEARCH FOUNDATION OF STATE UNIVERSITY OF NEW YORK; NEW YORK UNIVERSITY; GALDERMA LABORATORIES INC.; AND GALDERMA LABORATORIES, L.P.,)	
)	
Plaintiffs,)	
)	
v.)	
)	
IMPAX LABORATORIES, INC.,)	
)	
Defendant.)	
)	

C.A. No. 09 CV 00703-JJF

IMPAX LABORATORIES, INC.’S ANSWER AND COUNTERCLAIM

Defendant Impax Laboratories, Inc. (“Impax”) answers and responds to each of the allegations of plaintiffs The Research Foundation of State University of New York; New York University; Galderma Laboratories Inc.; and Galderma Laboratories, L.P. (collectively “Plaintiffs”) as follows:

1. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 1 of the Complaint, and on that basis denies the same.
2. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 2 of the Complaint, and on that basis denies the same.
3. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 3 of the Complaint, and on that basis denies the same.
4. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 4 of the Complaint, and on that basis denies the same.
5. Admits.

6. Paragraph 6 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Impax admits that this is a civil action for alleged infringement of U.S. Patents Nos. 7,232,572 (“the ‘572 patent”); 7,211,267 (“the ‘267 patent”); 5,789,395 (“the ‘395 patent”); and 5,919,775 (“the ‘775 patent”), copies of which are attached as Exhibits A-D to the Complaint; and that this action purports to be based upon the Patent laws of the United States, 35 U.S.C. §100 *et seq.* Impax denies all remaining allegations that may be set forth in paragraph 6 of the Complaint.

7. Paragraph 7 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Impax admits that this Court has subject matter jurisdiction over this action.

8. Admits that this Court has personal jurisdiction over it.

9. Admits.

10. Upon information and belief, admits.

11. Paragraph 11 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Impax admits that on June 19, 2007, the ‘572 patent, entitled “Methods of Treating Rosacea” was issued, and that CollaGenex Pharmaceuticals, Inc. is listed as assignee on the patent. Impax also admits that a copy of the ‘572 patent is attached as Exhibit A to the Complaint. Impax denies that the ‘572 patent was “duly and legally” issued, and denies all remaining allegations that may be set forth in paragraph 11 of the Complaint.

12. Admits.

13. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 13 of the Complaint, and on that basis denies the same.

14. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 14 of the Complaint, and on that basis denies the same.

15. Paragraph 15 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Impax admits that on May 1, 2007, the '267 patent, entitled "Methods of Treating Acne" was issued, and that CollaGenex Pharmaceuticals, Inc. is listed as assignee on the patent. Impax also admits that a copy of the '267 patent is attached as Exhibit B to the Complaint. Impax denies that the '267 patent was "duly and legally" issued, and denies all remaining allegations that may be set forth in paragraph 15 of the Complaint.

16. Admits.

17. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 17 of the Complaint, and on that basis denies the same.

18. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 18 of the Complaint, and on that basis denies the same.

19. Paragraph 19 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Impax admits that on August 4, 1998, the '395 patent, entitled "Method of Using Tetracycline Compounds for Inhibition of Endogenous Nitric Oxide Production" was issued, and that RF and Hospital for Joint Diseases are listed as assignees on the patent. Impax also admits that a copy of the '395 patent is attached as Exhibit C to the Complaint. Impax denies knowledge or information sufficient to form a belief as to the truth of the allegation as to whether Hospital for Joint Diseases is a predecessor in interest to NYU and on that basis denies the same. Impax denies that the '395 patent was "duly and legally" issued, and denies all remaining allegations that may be set forth in paragraph 19 of the Complaint.

20. Admits.

21. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 21 of the Complaint, and on that basis denies the same.

22. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 22 of the Complaint, and on that basis denies the same.

23. Paragraph 23 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Impax admits that on April 16, 1998, the '775 patent, entitled "Method of Inhibiting Expression of Inducible Nitric Oxide Synthase with Tetracycline" was issued, and that RF and Hospital for Joint Diseases are listed as assignees on the patent. Impax also admits that a copy of the '775 patent is attached as Exhibit D to the Complaint. Impax denies knowledge or information sufficient to form a belief as to the truth of the allegation as to whether Hospital for Joint Diseases is a predecessor in interest to NYU and on that basis denies the same. Impax denies that the '775 patent was "duly and legally" issued, and denies all remaining allegations that may be set forth in paragraph 23 of the Complaint.

24. Admits.

25. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 25 of the Complaint, and on that basis denies the same.

26. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 26 of the Complaint, and on that basis denies the same.

27. Impax restates its answers to paragraphs 1-26 of the Complaint as if fully set forth herein.

28. Admits.

29. Admits.

30. Impax avers that it made, and included in its ANDA, a Paragraph IV Certification that, in its opinion and to the best of its knowledge, the '572 patent is invalid, unenforceable, or will not be infringed by the manufacture, use, sale, offer for sale, or importation of Impax Laboratories, Inc.'s Doxycycline delayed-release capsules, 40 mg, for oral administration. Impax denies all remaining allegations that may be set forth in paragraph 30 of the Complaint.

31. Admits.

32. Impax avers that Plaintiffs received Impax's written Notification of Certification regarding the '572, '267, '395 and '775 patents; a detailed statement of the factual and legal bases of Impax's belief that the patents are not valid, are unenforceable, or will not be infringed, and an Offer of Confidential Access by letter of August 7, 2009. Impax denies all remaining allegations that may be set forth in paragraph 32 of the Complaint.

33. Denies.

34. Denies.

35. Denies. Impax further asserts that the "exceptional case" claim set forth in paragraph 35 of the Complaint fails to state a claim upon which relief can be granted. Concurrent with this Answer, Impax is filing a motion to dismiss this claim under Federal Rule of Civil Procedure 12(b)(6).

36. Impax restates its answers to paragraphs 1-35 of the Complaint as if fully set forth herein.

37. Impax avers that it made, and included in its ANDA, a Paragraph IV Certification that, in its opinion and to the best of its knowledge, the '267 patent is invalid, unenforceable, or will not be infringed by the manufacture, use, sale, offer for sale, or importation of Impax

Laboratories, Inc.'s Doxycycline delayed-release capsules, 40 mg, for oral administration.

Impax denies all remaining allegations that may be set forth in paragraph 37 of the Complaint.

38. Admits.

39. Denies.

40. Denies.

41. Denies. Impax further asserts that the "exceptional case" claim set forth in paragraph 41 of the Complaint fails to state a claim upon which relief can be granted.

Concurrent with this Answer, Impax is filing a motion to dismiss this claim under Federal Rule of Civil Procedure 12(b)(6).

42. Impax restates its answers to paragraphs 1-41 of the Complaint as if fully set forth herein.

43. Impax avers that it made, and included in its ANDA, a Paragraph IV Certification that, in its opinion and to the best of its knowledge, the '395 patent is invalid, unenforceable, or will not be infringed by the manufacture, use, sale, offer for sale, or importation of Impax Laboratories, Inc.'s Doxycycline delayed-release capsules, 40 mg, for oral administration.

Impax denies all remaining allegations that may be set forth in paragraph 43 of the Complaint.

44. Admits.

45. Denies.

46. Denies.

47. Denies. Impax further asserts that the "exceptional case" claim set forth in paragraph 47 of the Complaint fails to state a claim upon which relief can be granted.

Concurrent with this Answer, Impax is filing a motion to dismiss this claim under Federal Rule of Civil Procedure 12(b)(6).

48. Impax restates its answers to paragraphs 1-47 of the Complaint as if fully set forth herein.

49. Impax avers that it made, and included in its ANDA, a Paragraph IV Certification that, in its opinion and to the best of its knowledge, the ‘775 patent is invalid, unenforceable, or will not be infringed by the manufacture, use, sale, offer for sale, or importation of Impax Laboratories, Inc.’s Doxycycline delayed-release capsules, 40 mg, for oral administration. Impax denies all remaining allegations that may be set forth in paragraph 49 of the Complaint.

50. Admits.

51. Denies.

52. Denies.

53. Denies. Impax further asserts that the “exceptional case” claim set forth in paragraph 53 of the Complaint fails to state a claim upon which relief can be granted. Concurrent with this Answer, Impax is filing a motion to dismiss this claim under Federal Rule of Civil Procedure 12(b)(6).

DEFENSES

First Defense

The claims of the ‘572, ‘267, ‘395 and ‘775 patents in suit are invalid for failure to satisfy the requirements of Title 35 of the United States Code, including, without limitation, one or more of 35 U.S.C. §§ 101, 102, 103 and 112.

Second Defense

Impax has not directly or indirectly infringed any valid and enforceable claim of the ‘572, ‘267, ‘395 and ‘775 patents.

Third Defense

Any claim of infringement of the ‘572, ‘267, ‘395 and ‘775 patents under the doctrine of equivalents would be limited by prosecution history estoppel.

Fourth Defense

Each claim purporting to allege that this is an “exceptional case” fails to state a claim upon which relief can be granted. Concurrent with this Answer, Impax is filing a motion to dismiss those claims pursuant to Federal Rule of Civil Procedure 12(b)(6).

COUNTERCLAIM

(Declaratory Judgment)

For its counterclaim for declaratory judgment, Impax avers as follows:

1. This is a counterclaim for declaratory judgment pursuant to 28 U.S.C. §§ 2201 and 2202 for the purpose of determining an actual and justiciable controversy between the parties. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

Claim for Relief

2. Plaintiffs brought an action against Impax for alleged infringement of the ‘572, ‘267, ‘395 and ‘775 patents, based on the submission of ANDA No. 91-447 by Impax Laboratories, Inc.

3. The claims of the ‘572, ‘267, ‘395 and ‘775 patents are invalid for failure to satisfy the requirements of Title 35 of the United States Code, including, without limitation, one or more of 35 U.S.C. §§ 101, 102, 103 and 112.

4. Impax has not directly or indirectly infringed any valid and enforceable claim of the ‘572, ‘267, ‘395 and ‘775 patents.

5. The manufacture, use, offer for sale, sale and/or importation of the drug product that is the subject of ANDA No. 91-447 would not infringe any valid and enforceable claim of the '572, '267, '395 and '775 patents.

6. A definite and concrete, real and substantial, justifiable controversy exists between the parties regarding, *inter alia*, the invalidity and non-infringement of the '572, '267, '395 and '775 patents that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.


PRAYER FOR RELIEF

WHEREFORE, Impax prays for a judgment that:

- A. Dismisses the Complaint with prejudice;
- B. Declares that the claims of the '572, '267, '395 and '775 patents are invalid;
- C. Declares that Impax has not infringed any valid and enforceable claim of the '572, '267, '395 and '775 patents;
- D. Declares that the manufacture, use, offer for sale, sale and/or importation of the drug product that is the subject of ANDA No. 91-447 would not infringe any valid and enforceable claim of the '572, '267, '395 and '775 patents;
- E. Awards Impax its costs and attorneys fees; and
- F. Awards Impax such other and further relief that the Court deems just and proper.

Dated: October 13, 2009

By:



Mary B. Matterer (#2696)

MORRIS JAMES LLP

500 Delaware Avenue, Suite 1500

Wilmington, Delaware 19801

Tel. (302) 888-6800

mmatterer@morrisjames.com

Attorneys for Impax Laboratories, Inc.

Of counsel:

Jeffrey Alan Hovden

Michael F. Sarney

KATTEN MUCHIN ROSENMAN LLP

575 Madison Avenue

New York, New York 10022

Tel: (212) 940-8800